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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,857	RENAULT, BEATRICE	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-26* is/are rejected.

7)☒ Claim(s) *6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031113*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of SEQ ID NO:2, including claims 2 and 7, including the variants of claim 3, including SEQ ID NO:2 as recited in claim 4, part b, and including the mixtures of claim 4, parts d and e, to the extent that they require SEQ ID NO:2, in the reply filed on January 10, 2005 is acknowledged. The traversal is on the ground(s) that there would be no serious burden upon the examiner in searching and examining the nonelected sequences. This is not found persuasive because each of the nonelected sequences would require an additional sequence search and evaluation of the results, which constitutes an undue burden upon the examiner. Group policy is to search one sequence identified by SEQ ID NO per application.

The requirement is still deemed proper and is therefore made FINAL.

2. The Sequence Listing filed April 7, 2004 has been approved.

3. In the title of the invention in the Application Data Sheet, the word "Wrinkles" is misspelled and should be corrected.

4. This application claims benefit to a provisional application No. 60/427,575, filed on November 20, 2002, in a language other than English. Applications that claim benefit of a provisional application filed in a non-English language must include an English translation of the non-English language provisional application and a statement that the translation is accurate. See 37 CFR 1.78(a)(5). The English translation and a statement that the translation is accurate as required by 37 CFR 1.78(a)(5) is missing. Applicant must supply the missing English translation and the statement that the translation is accurate in the reply to this Office action prior to the expiration of the time period set in this Office action. See MPEP 201.11(F).

5. The disclosure is objected to because of the following informalities: A Brief Description of the Drawing is needed in the specification, as required by 37 CFR 1.74. SEQ ID NOS need to

be inserted after the amino acid sequences at pages 24-27 which are subject to the sequence disclosure rules. See 37 CFR 1.821(d). Appropriate correction is required.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 1, 13, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Montal et al (U.S. Patent No. 6,169,074) as evidenced by the Ji et al article (Diabetes, Vol. 51, pages 1425-1436). Montal et al teach a pharmaceutical composition comprising a peptide consisting of SEQ ID NO:9. The compositions can include sodium chloride free buffers and antioxidants. See, e.g., column 10, line 62 - column 11, line 20, and claims 7 and 8. As can be seen by comparing SEQ ID NO:9 to SEQ ID NO:1, which is the amino acid sequence of SNAP-

25, SEQ ID NO:9 of Montal et al corresponds to SNAP-$25_{187-206}$. The Ji et al article teaches that a peptide corresponding to SNAP-$25_{198-206}$ has calcium channel inhibitory activity. See, e.g., the Abstract. Accordingly, SEQ ID NO:9 of Montal et al would have been expected inherently to possess calcium-channel inhibitory activity because it comprises the peptide which the Ji et al article teaches possesses calcium-channel inhibitory activity. The peptide of Montal et al consisting of SEQ ID NO:9 satisfies both requirements (i) and (ii) of instant claim 1, and Applicant's claimed composition is therefore deemed to be anticipated by the pharmaceutical composition of Montal et al. Sufficient evidence of similarity is deemed to be present between the pharmaceutical composition of Montal and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than that of Montal et al. Note that the claims do not require the peptide and the calcium-channel inhibitor to be different molecules. Note also, with respect to the phrase "for topical application to skin" in Applicant's claims 1 and 19 and the other intended use limitations in Applicant's claims 19-21, that an intended use limitation does not impart patentability to product claims or to method of making claims where the product made is otherwise anticipated by or obvious over the prior art.

8. Claims 8-11 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Montal et al (U.S. Patent No. 6,169,074) as evidenced by the Ji et al article (Diabetes, Vol. 51, pages 1425-1436). Application of the references is the same as in the above rejection of claims 1, 13, and 19-21. Montal et al do not teach concentrations for the components of the disclosed pharmaceutical compositions. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations for

the components of the pharmaceutical compositions of Montal et al because component concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

9. Claims 1-5 and 8-26 are rejected under 35 U.S.C. 103(a) as being obvious over Besne (U.S. Patent Application Publication 2003/0235599). Besne teaches compositions for smoothing out expression wrinkles and fine lines in the skin. The compositions are required to comprise a sapogenin, which is a dermo-relaxant. The compositions can comprise the same adjuvants in the same concentrations claimed by Applicant, and can be in the same forms claimed by Applicant. The compositions can comprise UVA-active and UVB-active photoprotective agents in a concentration of 12.5%. The compositions can comprise muscle relaxants such as alverine and its salts, manganese gluconate, and the hexapeptide Argireline. See, e.g., the Abstract, paragraphs [0019], [0031], [0033], [0071], and [0090]; Example 2; and claim 8. Argireline has the same amino acid sequence as Applicant's SEQ ID NO:2. Besne does not teach compositions comprising multiple muscle relaxants, i.e. comprising the hexapeptide Argireline plus at least one of alverine and it salts or manganese gluconate. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to form compositions according to Besne comprising multiple muscle relaxants, i.e. comprising the hexapeptide Argireline plus at least one of alverine and it salts or manganese gluconate, because Besne discloses all three components to be useful in the wrinkle-treating compositions, because it is prima facie obvious to use a mixture of components each of which has been used individually for the same purpose (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the resulting compositions has only the expected activity of smoothing out expression wrinkles and

fine lines in the skin. Besne does not teach concentrations for the muscle relaxant components of the disclosed compositions. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations for the muscle relaxant components of the compositions of Besne because component concentration is an art-recognized result-effective variable which is routinely determined and optimized in the cosmetic arts.

10. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being obvious over the French Patent 2,838,344. The French Patent '344 is the equivalent of Besne (U.S. Patent Application Publication 2003/0235599) applied above. However, the French Patent '344 is currently available as prior art under 35 U.S.C. 102(a), and unlike Besne, the provisos of 35 U.S.C. 103(c) do not currently apply to this rejection over the French Patent '344.

11. Claims 1-5, 12, 13, 15, 16, and 19-26 are rejected under 35 U.S.C. 102(a) and (b) as being anticipated by "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand", each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news". "British Nursing News Online-News Archives", page 3, teaches that a cosmetic product named "Faux-Tox", a cream, was supplied from New York and was on sale in Edinburgh at least by November 3, 2002. The cosmetic product reduces muscle contractions which cause wrinkles, and smoothes out fine lines. "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand", teaches a cosmetic product named "Wrinkle Relax", formerly called "Faux-Tox", and gives a copyright date of 2001, indicating that the cosmetic product was on sale in this country at least in the year 2001. The cosmetic product prevents fine lines and reduces the

appearance of wrinkles, and is most effective in the orbital eye area and the forehead. "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" teaches that a cosmetic product named "Wrinkle Relax", aka 'Faux-Tox", is comprised of Acetyl Hexapeptide-3 and magnesium ascorbyl, and additionally contains glycerin and propylene glycol (which are moisturizers), water (a solvent), and Red #40 (a dyestuff). "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news" teaches that cosmetic product named "Wrinkle Relax", aka 'Faux-Tox", is comprised of Argireline and magnesium ascorbyl. Acetyl Hexapeptide-3/Argireline correspond to Applicants' peptide having the amino acid sequence SEQ ID NO:2. Magnesium ascorbyl corresponds to Applicants' magnesium salt which is a calcium channel inhibitor. A "cream" is defined in Stedman's Medical Dictionary, 27th edition, as being a semi-solid emulsion, either of the O/W or the W/O type. Because water is listed as the most predominant ingredient by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax", Wrinkle Relax/Faux-Tox would have been expected inherently to be in the form of an O/W emulsion.

12. Claims 8-11 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand", each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news". Application of the references is the same as in the above rejection of claims 1-5, 12, 13, 15, 16, and 19-26. The references do not disclose concentrations for the various components present in Wrinkle Relax/Faux-Tox. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations for the

components of Wrinkle Relax/Faux-Tox because component concentration is an art-recognized result-effective variable which is routinely determined and optimized in the cosmetic arts.

13. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over "British Nursing News Online-News Archives" or "DDF Wrinkle Relax (formerly Faux-Tox) by BeautyLand", each as evidenced by "Skin Care Products Recommended by Dermatologists - DDF - Wrinkle Relax" and "DDF Wrinkle Relax/Faux-Tox - cosmetic surgery news" as applied against claims 1-5, 12, 13, 15, 16, and 19-26 above, and further in view of Simon et al (U.S. Patent No. 5,730,972). The references applied in the above rejection do not teach the presence of a UVA-active photoprotective agent. Simon et al teach including a UVA screening agent in concentrations of 0/1% to 10% in compositions used to combat skin marks, such as wrinkles and fine lines, and/or aging of the skin. See, e.g., the abstract, column 1, line 66 - column 2, line 2; and claims 1 and 10. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to include the UVA screening agents of Simon et al in Wrinkle Relax/Faux-Tox because the UVA screening agents of Simon et al are used in cosmetic compositions with similar uses to Wrinkle Relax/Faux-Tox, and because including the UVA screening agents of Simon et al would have the benefit of providing an additional mechanism whereby wrinkles and fine lines could be prevented.

14. Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest a composition comprising at least one peptide comprising at least one amino acid sequence derived from SNAP 25 and magnesium gluconate. The prior art of record does not teach the use of magnesium

gluconate for any purpose analogous to those of the compositions taught in the prior art applied above, and thus there is no motivation to include magnesium gluconate with the peptide-containing compositions of the prior art applied above.

The Ji et al article (Biochem. Biophys. Res. Comm., Vol. 306, pages 298-302) is cited as art of interest, teaching that intact SNAP-25 has calcium-channel inhibitory properties. The Blanes-Mira et al article (Int. J. Cosmetic Science, Vol. 24, pages 303-310) is cited as art of interest, teaching that Argireline has antiwrinkle activity.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 3, 2005